



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification 7 :</b> <b>A61B 17/064, 17/22, A61F 2/06</b>	<b>A2</b>	<b>(11) International Publication Number:</b> <b>WO 00/07506</b> <b>(43) International Publication Date:</b> 17 February 2000 (17.02.00)
<b>(21) International Application Number:</b> PCT/GB99/02544 <b>(22) International Filing Date:</b> 3 August 1999 (03.08.99)  <b>(30) Priority Data:</b> 9816802.4      3 August 1998 (03.08.98)      GB 9816800.8      3 August 1998 (03.08.98)      GB  <b>(71) Applicant (for all designated States except US):</b> ANSON MEDICAL LTD. [GB/GB]; 68 Milton Park, Abingdon, Oxon OX14 4RX (GB).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> ANSON, Antony, Walter [GB/GB]; 101 Martindale Road, Hounslow, Middlesex TW4 7EZ (GB). HOPKINSON, Brian, Ridley [GB/GB]; 18 Victoria Crescent, Sherwood, Nottingham NG5 4DA (GB). YUSUF, Waquar, Syed [PK/GB]; 2 Kings Down Mount, Wollaton, Nottingham (GB).  <b>(74) Agent:</b> TOLLETT, Ian; Williams, Powell & Associates, 4 St. Paul's Churchyard, London EC4M 8AY (GB).		<b>(81) Designated States:</b> AU, JP, KR, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>
<b>(54) Title:</b> DEVICES AND METHODS FOR THE REPAIR OF ARTERIES  <div data-bbox="446 1171 1128 1732" data-label="Image"> </div> <b>(57) Abstract</b> <p>A device for retaining a graft on an artery, comprising a first part for contacting the graft and a second part for contacting the artery when the device is pierced radially through the graft and the artery wall, the first and second parts being connected by a resilient member, wherein the resilient member biases the first and second parts towards each other into a retaining configuration such that in use the artery and the graft are retained together between the first and second parts of the device, and wherein the first and second parts are moveable into an open configuration in which they are further apart than in the retaining configuration to enable the device to be conveyed along an artery.</p>		

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Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>7</sup> : <b>A61B 17/064, 17/22, A61F 2/06, A61M 29/00</b>		<b>A3</b>	(11) International Publication Number: <b>WO 00/07506</b>
			(43) International Publication Date: 17 February 2000 (17.02.00)
(21) International Application Number: PCT/GB99/02544		(81) Designated States: AU, JP, KR, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 3 August 1999 (03.08.99)			
(30) Priority Data: 9816802.4 3 August 1998 (03.08.98) GB 9816800.8 3 August 1998 (03.08.98) GB		<b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(71) Applicant (for all designated States except US): ANSON MEDICAL LTD. [GB/GB]; 68 Milton Park, Abingdon, Oxon OX14 4RX (GB).		(88) Date of publication of the international search report: 18 May 2000 (18.05.00)	
(72) Inventors; and (75) Inventors/Applicants (for US only): ANSON, Antony, Walter [GB/GB]; 101 Martindale Road, Hounslow, Middlesex TW4 7EZ (GB). HOPKINSON, Brian, Ridley [GB/GB]; 18 Victoria Crescent, Sherwood, Nottingham NG5 4DA (GB). YUSUF, Waquar, Syed [PK/GB]; 2 Kings Down Mount, Wollaton, Nottingham (GB).			
(74) Agent: TOLLETT, Ian; Williams, Powell & Associates, 4 St. Paul's Churchyard, London EC4M 8AY (GB).			
(54) Title: DEVICES AND METHODS FOR THE REPAIR OF ARTERIES			
(57) Abstract			
<p>A device for retaining a graft on an artery, comprising a first part for contacting the graft and a second part for contacting the artery when the device is pierced radially through the graft and the artery wall, the first and second parts being connected by a resilient member, wherein the resilient member biases the first and second parts towards each other into a retaining configuration such that in use the artery and the graft are retained together between the first and second parts of the device, and wherein the first and second parts are moveable into an open configuration in which they are further apart than in the retaining configuration to enable the device to be conveyed along an artery.</p>			

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EE	Estonia						

PCT/GB 99/02544

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/064 A61B17/22 A61F2/06 A61M29/00

IPC 7    A61B    A61F    A61M

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Category <sup>3</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
-----------------------	--	-----------------------

X	US 3 527 223 A (SHEN) 8 September 1970 (1970-09-08) figures 1,3,5 ---	1-3,6-12
X	US 5 632 746 A (PYKA) 27 May 1997 (1997-05-27) figures 212,321 ---	1-4,6 17,21, 31,37
X	US 3 716 058 A (TANNER) 13 February 1973 (1973-02-13) column 2, paragraph 3; figure 4 ---	1,4,5
A	FR 2 746 292 A (PEROUSE) 26 September 1997 (1997-09-26) figures 2,7,8,18	1,4

- / - -

☒ Patent family members are listed in annex.

<sup>2</sup> Special categories of cited documents :

"P" document published prior to the international filing date but later than the priority date claimed

"&" document member of the same patent family

Date of mailing of the international search report

28. 03. 2000

Authorized officer

Barton, S

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/02544

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 618 311 A (GRYSKIEWICZ) 8 April 1997 (1997-04-08) figure 1 ---	5
A	FR 2 725 126 A (MAI) 5 April 1996 (1996-04-05) figure 9C ---	8-11
A	US 5 531 760 A (ALWAFATIE) 2 July 1996 (1996-07-02) ---	
X	US 4 921 484 A (HILLSTEAD) 1 May 1990 (1990-05-01)  column 1, paragraph 1 column 5, line 18 column 5, line 53 - line 58 ---	13-16, 19-22, 28-30, 33-37
A	US 5 330 490 A (WILK) 19 July 1994 (1994-07-19) column 9, paragraph 2; figures 9-12 ---	31
X	US 5 222 971 A (WILLARD) 29 June 1993 (1993-06-29) column 4, line 39 - line 43 column 11, line 59 - line 66 column 13, line 35 - line 39 ---	13,22
X	EP 0 820 729 A (TARGET) 28 January 1998 (1998-01-28) column 8, paragraph 3 - column 9, paragraph 3 ---	13,20, 28,36
A	US 5 042 707 A (TAHERI) 27 August 1991 (1991-08-27) ---	13,21, 28,41
A	US 5 192 291 A (PANNEK) 9 March 1993 (1993-03-09) -----	

# INTERNATIONAL SEARCH REPORT

Inte. lional application No.  
PCT/GB 99/02544

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-27, 43-47  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:  
1-22, 28-37, 48-50
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-12,48,50

Staple

2. Claims: 13-22

Catheter support

3. Claims: 28-37,49

Dilator

4. Claims: 38-42,50

Spiral fixing



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 99/02544

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3527223 A	08-09-1970	NONE	
US 5632746 A	27-05-1997	US 5486183 A	23-01-1996
		US 5509923 A	23-04-1996
		US 5749879 A	12-05-1998
		US 5904690 A	18-05-1999
		US 5601572 A	11-02-1997
		US 6004330 A	21-12-1999
		US 5720754 A	24-02-1998
		AU 664358 B	16-11-1995
		AU 8918191 A	28-04-1992
		CA 2093821 A	10-04-1992
		EP 0554361 A	11-08-1993
		JP 6502354 T	17-03-1994
		WO 9205828 A	16-04-1992
		US 5820628 A	13-10-1996
		AT 131370 T	15-12-1995
		CA 2064830 A	17-02-1991
		DE 69024219 D	25-01-1996
		DE 69024219 T	07-11-1996
		EP 0487645 A	03-06-1992
		JP 4507363 T	24-12-1992
		WO 9102493 A	07-03-1996
US 3716058 A	13-02-1973	NONE	
FR 2746292 A	26-09-1997	NONE	
US 5618311 A	08-04-1997	NONE	
FR 2725126 A	05-04-1996	NONE	
US 5531760 A	02-07-1996	NONE	
US 4921484 A	01-05-1990	NONE	
US 5330490 A	19-07-1994	NONE	
US 5222971 A	29-06-1993	AU 9019391 A	28-04-1992
		CA 2091894 A	10-04-1992
		EP 0552307 A	28-07-1993
		JP 6502333 T	17-03-1994
		WO 9205829 A	16-04-1992
		US 5449372 A	12-09-1995
EP 820729 A	28-01-1998	US 5972019 A	26-10-1999
		AU 3081897 A	05-02-1998
		CA 2211516 A	25-01-1998
		EP 0914807 A	12-05-1999
		JP 10151136 A	09-06-1998
		NO 973428 A	26-01-1999
US 5042707 A	27-08-1991	NONE	
US 5192291 A	09-03-1993	NONE	

## TENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 18 April 2000 (18.04.00)	
<b>International application No.</b> PCT/GB99/02544	<b>Applicant's or agent's file reference</b> IT/N8665
<b>International filing date</b> (day/month/year) 03 August 1999 (03.08.99)	<b>Priority date</b> (day/month/year) 03 August 1998 (03.08.98)
<b>Applicant</b> ANSON, Antony, Walter et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
03 March 2000 (03.03.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

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REC'D 22 NOV 2000

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference IT/mh/n8665	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB99/02544	International filing date (day/month/year) 03/08/1999	Priority date (day/month/year) 03/08/1998
International Patent Classification (IPC) or national classification and IPC A61B17/064		
Applicant ANSON MEDICAL LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 11 sheets, including this cover sheet.
  - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  03/03/2000	Date of completion of this report  20.11.2000
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Kempin, H-F  Telephone No. +49 89 2399 2716  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB99/02544

**I. Basis of the report**

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

**Description, pages:**

1-20 as originally filed

**Claims, No.:**

1-47 with telefax of 30/10/2000

**Drawings, sheets:**

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB99/02544

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 20-25, 35-44, 45(if referring to non-searched claims), 46, 47.

because:

- ☒ the said international application, or the said claims Nos. 20, 46, 47 relate to the following subject matter which does not require an international preliminary examination (*specify*):  
**see separate sheet**
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 21-25, 35-44.
2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB99/02544

- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-20, 26-34, 45-47.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims
	No:	Claims 12-19
Inventive step (IS)	Yes:	Claims 1-11, 45
	No:	Claims 12-19, 26-34
Industrial applicability (IA)	Yes:	Claims 1-19, 26-34, 45
	No:	Claims

**2. Citations and explanations**  
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**Concerning Section I (Basis of report)**

The amendments filed with the fax dated 30.10.2000 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

The features of the characterising portion of **claim 12** were originally disclosed in claim 34, which was **not** dependent on original claim 13, now forming the first part of claim 12 together with features of original claim 16. Therefore, the original claims cannot entirely support the amendment. Furthermore, means for bowing the central section of the support member radially outwards were not originally disclosed in the description or figures either, such means were only disclosed in connection with the dilator (see the description of the function of the pulling wire 119 on pages 17, 18) but not the stabiliser. There is not incitation anywhere that the pulling wire 119 can be used in connection with the supporting/stabilizer device of figure 10. The pusher-wire mentioned at the foot of page 14 in connection with the fixator delivery tube is only used for pushing out the fixator delivery tube.

**Concerning Section III (Non-establishment of opinion ...)**

Claim 46 relates to the use of a device to dilate the walls of an artery. A use claim corresponds to a method claim; see the PCT Preliminary Examination Guidelines CIII-3.1. Claim 46 thus relates to an activity comprising a surgical step, which is dilation of a blood vessel. Accordingly, the claim is directed to subject-matter mentioned in Rule 67.1(iv) PCT. Under the terms of Art.34(4)(a)(i) PCT an International Preliminary Examining Authority is not requested to carry out an examination of such a claim. Claims 20 and 47 relate to the use of a device to support a catheter within a conduit or the use of a device to retain a graft on the walls on an artery or vein, respectively, and thus also implicitly define a surgical activity. Consequently, an examination is not requested as for claims 20 and 46.

**Concerning Section IV (Lack of unity ...)**

1. The International Search Report (ISR) was not established for all claims. Certain

claims were not the object of a search since they relate either to a method for treatment of the human or animal body by surgery, or the required additional search fee was not paid.

2. Only claims in respect of which an ISR was established can be examined. The searched claims comprise 6 independent claims which are claims 1, 12, 20, 26, 46, and 47 (The use claims are considered independent although they refer back to other claims because they refer to claims of a different category). Each independent claim defines an invention since this is the purpose of an independent claim.
3. Under the provisions of Rule 13.1 PCT a group of inventions may be claimed in one application if they are so linked as to form a single general inventive concept. Rule 13.2 of the PCT defines in more detail what is meant with "a single general inventive concept". This concept must find expression in the claims in the same or corresponding special technical features, where the expression "special technical features" means the features which define the inventive contribution that the claimed invention makes over the prior art; see also the PCT Preliminary Examination Guidelines PCT/GL/3 Chapter III-7.1 and 7.2. However, the set of claims forming the basis for examination is objectionable under Rule 13.1-3 PCT since it comprises multiple (groups of) inventions:
  1. Claims 1-11, 45 relate to a staple which is distinguished over the prior art in that it comprises a plurality of first parts.
  2. Claims 12-19 define a catheter support with a locating member and a plurality of support members.
  3. Claims 26-34 are directed to a dilator which differs from the prior art by additionally means to bow the central section of the dilating members radially outwards .

The features of these claims or groups of claims cannot be subsumed under a single general inventive concept since the number of first part on a staple has nothing to do with the design of a catheter support, or means for bowing out the



central section of a dilator.

**Concerning Section V (Reasoned statement ...)**

**First invention as defined in claims 1-11, 45**

**1. Reference is made to the following documents:**

D1: US-A-5 632 746 (MIDDLEMAN, PYKA ET AL. ) 27 May 1997

D2: US-A-3 527 223 (SHEIN) 8 September 1970

D3: US-A-4 921 484 (HILLSTEAD) 1 May 1990

D4: US-A-4 590 938 (SEGURA ET AL.) 27 May 1986

Document D4 was not cited in the international search report.

**1.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):**

A device for retaining tissue on both sides of an incision, comprising a first part for contacting the tissue on one side of the incision and a second part for contacting the tissue on the other side of the incision when the device is pierced through the tissue on both sides of the incision (see reference numeral 8 in figures 2-17A - 17C), the first and second part being connected by a resilient member (see column 25, lines 11, 20 and column 2, lines 51-58), wherein the resilient member biases the first and second part towards each other into a retaining configuration such that in use the tissue parts are retained together between the first and second parts of the device, and wherein the first and second parts are movable into an open configuration in which they are further apart than in the retaining configuration (compare figures 2-12A and 2-12B) to enable the device to be conveyed along an artery (see column 25, lines 15-18). Although it is not expressly mentioned in D1 is that the device can be used for retaining a graft on an artery, it is considered that the known clip is also suitable for retaining graft on an artery so that this feature is implicitly known from D1; see the PCT Preliminary Examination Guidelines CIV-7.6

The device of claim 1 differs from the known device in that it comprises a plurality of first parts. This solves the problem of retaining a graft on an artery in a more secure manner. The distinguishing feature of claim 1 is neither known from, nor rendered obvious by, the available prior art. Although document D2 discloses a wire-like body with sliced ends which can be straightened to align with the body portion (see column 1, line 67 to column 2, line 9), it is considered that D2 discloses a device which is unsuitable for retaining a graft on an artery since it relates to a temporary ear stud of ornamental appearance. D2 would thus not be considered by the skilled person.

Dependent claims 2-11 relate to preferred embodiments of the device of claim 1.

Therefore, claims 1-11 appear to satisfy the requirements of Art.33(2) (novelty), 33(3) (inventive step) and 33(4) (industrial applicability) of the PCT.

- 1.2 Claim 45 relates to a kit comprising at least two of the devices of any of claims 1-11, and thus appears to satisfy the requirements of Art.33(2) (novelty), 33(3) (inventive step) and 33(4) (industrial applicability) of the PCT for the same reasons as these claims.

## **Second invention as defined in claims 12-19**

- 2.1 In the following paragraph the combination of original claims 13 and 16, now claim 12, is discussed; see Basis of Report, point 3.

From document D1 there is known a device for use with a catheter (see figures 5-1, 5-2 and column 46, lines 50-53), the device having a locating member for locating the device with respect to the catheter (see column 46, lines 47-50) and a plurality of support members for supporting the catheter on the inner wall of an artery (see loops 116 and column 47, lines 28-30), wherein each support member and the locating member are connected by a resilient member which biases the support member towards the artery wall (see column 45, lines 9-23).

Although not expressly mentioned in document D1, the device known from figures 5-1 and 5-2 of D1 and described in column 45, line 9 to column 47, line 52 is

suitable to be used as a support for a catheter. In this context it is referred to the access for additional devices mentioned in the paragraph bridging columns 46 and 47. If the loops is extended from the catheter in an artery of suitable dimension they necessarily support the catheter when another instrument is inserted through the additional access provided within the catheter housing. The catheter support functionality is thus implicit from D1.

Therefore, the device of claim 12 does not appear to satisfy the requirement of Art.33(2) PCT (novelty).

- 2.2 Dependent claims 13-19 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:

claim 13, 14: see figure 5-1;

claim 15: see column 47, lines 42-47;

claims 16, 17: see again figure 5-2;

claim 18: see column 47, lines 47-53;

claim 19: see column 45, lines 37-39 and 60-63.

**Third invention as defined in claims 26-34.**

- 3.1 A device having the features of the first part of claim 26 is known from D1 (figures 5-1, 5-2 and column 45, line 9 to column 47, line 53). The particular intended use defined in claim 26 is implicit in the disclosure of D1 since the known retractor is also suitable for dilating an artery.

The device of claim 26 differs from the known device in that it additionally comprises means which can cause the central section of the dilating member to bow radially outwards in order to apply increased outward pressure, as defined in detail in the second part of claim 26.

Thereby, the problem of improving the dilating effect of the known device is solved. However, the distinguishing features have already been employed for the same purpose in a similar device, see document D3, column 4, lines 20-30. It

would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to claim 26. The subject-matter of claim 26 does therefore not involve an inventive step (Article 33(3) PCT).

- 3.2 Dependent claims 27-34 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, the reasons being as follows:

claim 27, 28: see D1, figure 5-1;

claim 29: see D1, column 47, lines 42-47;

claim 30: see again figure 5-2 of D1;

claim 31: see document D4 (cited in D1 in column 44, lines 58, 59), reference numerals 20, 21;

claim 32: see again D3, column 4, lines 20-30

claim 33: see D1 column 47, lines 47-53;

claim 34: see D1 column 45, lines 37-39 and 60-63.

**Concerning Section VII (Certain defects ...)**

1. The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
4. The description is not in conformity with the claims as required by Rule 5.1(a)(iii)

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB99/02544

PCT.

## CLAIMS

1. A device for retaining a graft on an artery, comprising a first part for contacting the graft and a second part for contacting the artery when the device is pierced radially through the graft and the artery wall, the first and second parts being connected by a resilient member, wherein the resilient member biases the first and second parts towards each other into a retaining configuration such that in use the artery and the graft are retained together between the first and second parts of the device, and wherein the first and second parts are moveable into an open configuration in which they are further apart than in the retaining configuration to enable the device to be conveyed along an artery,

characterised in that the device comprises a plurality of first parts.

2. A device as claimed in claim 1, wherein in the open configuration the first parts, the resilient member and the second part are disposed substantially on an axis.

3. A device as claimed in claim 1 or 2, wherein in the retaining configuration at least one of the first and second parts forms an arcuate shape.

4. A device as claimed in any preceding claim, wherein at least a portion of at least one of the first and second parts is sharpened to enable said part to pierce a graft and an artery.

5. A device as claimed in claim 4, wherein both the first and the second parts are so sharpened.

6. A device as claimed in any preceding claim, wherein the device is formed from a wire.

7. A device as claimed in any preceding claim, wherein the device is formed from a shape memory alloy.

8. A device as claimed in any preceding claim, wherein the device has a plurality of second parts.

9. A device as claimed in claim 8, wherein the device has equal numbers of first and second parts.

10. A device as claimed in claim 8 or 9, wherein said plurality of parts are integral or welded together.

11. A device as claimed in claim 9, which is formed of a plurality of sets, each set comprising a first part, a resilient member and a second part, wherein the plurality of sets are linked together by a weld, a sheath, a bush, a crimp or by wire.

12. A device for supporting a catheter within an artery or arterial graft, the device having a locating member for locating the device with respect to the catheter and a plurality of support members for supporting the catheter on the inner wall of the artery or graft, wherein each support member and the locating member are connected by a resilient member which biases the support member towards the artery wall,

characterised in that the device additionally comprises means for reducing the distance between the end of each support member distal to the locating member and the end of said support member proximate the locating member, thereby causing the central section of said support member to bow radially outwards with respect to the locating member.

13. A device as claimed in claim 12, wherein the locating member is adapted to fit axially inside a catheter.

14. A device as claimed in claim 13, wherein the support members and the locating member are moveable into a position in which the support members, the resilient members and the locating member are disposed substantially on an axis, to enable the device to be conveyed along a catheter.

15. A device as claimed in any of claims 12 to 14, wherein each support member is connected to at least one other support member by the end of the support member distal to the locating member.

16. A device as claimed in claim 15, comprising at least one resilient wire disposed in a loop with the ends of the wire being locatable in an end of a catheter, wherein in use the sides of the loop contact the artery or graft to support the catheter within the artery or graft.

17. A device as claimed in any of claims 12 to 16, wherein said plurality of support members are disposed such that in use the device supports the catheter substantially centrally within an artery.

18. A device as claimed in any of claims 12 to 17, wherein each support member has a non-traumatic contact surface for contacting the artery wall.

19. A device as claimed in any of claims 12 to 18 which is formed from a shape memory alloy or a super elastic material.

20. The use of a device as claimed in any of claims 12 to 19 to support a catheter within a conduit.

21. A method for delivering a device as claimed in any of claims 1 to 11 to a locus of a conduit, comprising the steps of moving said first parts and second part of the device into said open configuration, inserting the device into a catheter, positioning an end of the catheter at the locus, and moving the device down the catheter until the device emerges from said end of the catheter at the locus.

22. A method as claimed in claim 21, wherein said end of the catheter is angled radially relative to the axis of the catheter.



23. A method as claimed in claim 21 or 22, additionally comprising the step of housing the catheter within a sheath catheter.

24. A method as claimed in any of claims 21 to 23, comprising the step of inserting a plurality of said devices into the catheter, and inserting a pushing element sufficiently far into the catheter to contact and apply pressure to the device closest to the pushing element in order to cause a device to be ejected from the end of the catheter distal to the pushing element at the locus of the conduit.

25. A method as claimed in any of claims 21 to 24, additionally comprising the step of employing a device as claimed in any of claims 12 to 19 to support the catheter within the conduit.

26. A device for dilating an artery when delivered translumenally to a locus of an artery by means of a catheter, having a locating member for locating the device with respect to the catheter and a plurality of dilating members, each of which is connected to the locating member by a resilient member which biases the dilating member towards and into contact with the inner artery wall, wherein in use the resilient members cause the dilating members to apply outward pressure to the inner artery wall in order to dilate the artery

characterised in that the device additionally comprises means for reducing the distance between the end of each dilating member distal to the locating member and the end of said dilating member proximate the locating member, thereby causing the central section of said dilating member to bow radially outwards with respect to the locating member in order to apply increased outward pressure on the inner wall of the artery when the device is in use.

27. A device as claimed in claim 26, wherein the locating member is adapted to fit axially inside a catheter.

28. A device as claimed in claim 26 or 27, wherein the members and the locating member are moveable into a position in which the locating member, the resilient members and the dilating members are disposed substantially on an axis, to enable the device to be conveyed along a catheter.
29. A device as claimed in any of claims 26 to 28, wherein each dilating member is connected to at least one other dilating member by the end of the dilating member distal to the locating member.
30. A device as claimed in any of claims 26 to 29, comprising at least one resilient wire disposed in a loop with the ends of the wire being locatable in an end of a catheter, wherein in use the sides of the loop contact the inner artery wall and apply outward pressure thereto in order to dilate the artery.
31. A device as claimed in any of claims 26 to 30, wherein said plurality of dilating members are distributed equally radially about the locating member.
32. A device as claimed in any of claims 26 to 31, wherein said means for reducing the distance is an additional connection between the end of each dilating member distal to the locating member and the locating member.
33. A device as claimed in any of claims 26 to 32, wherein each dilating member has a non-traumatic contact surface for contacting the artery wall.
34. A device as claimed in any of claims 26 to 33 which is formed from a shape memory alloy or a super elastic material.
35. A device for retaining a graft on an artery, comprising an elongate member formed of a resilient material which biases said member into a helical configuration, at least one end of the member being sharpened to enable the member to pierce through the graft and the artery

wall, wherein the member is moveable into an open configuration in which it can be conveyed along an artery.

36. A device as claimed in claim 35, wherein in the helical configuration the device has less than 10 turns.

37. A device as claimed in claim 35 or 36, in which the diameter of the helix formed by the member is no less than about seven times the cross-sectional diameter of the member.

38. A device as claimed in any of claims 35 to 37, wherein the member is formed from a shape memory alloy.

39. A device as claimed in any of claims 35 to 38, wherein in said open configuration the device is substantially straight.

40. A method for delivering a device as claimed in any of claims 35 to 39 to a locus of a conduit, comprising the steps of moving said helical member into said open configuration, inserting the device into a catheter, positioning an end of the catheter at the locus, and moving the device down the catheter until the device emerges from said end of the catheter at the locus.

41. A method as claimed in claim 40, wherein said end of the catheter is angled radially relative to the axis of the catheter.

42. A method as claimed in claim 40 or 41, additionally comprising the step of housing the catheter within a sheath catheter.

43. A method as claimed in any of claims 40 to 42, comprising the step of inserting a plurality of said devices into the catheter, and inserting a pushing element sufficiently far into the catheter to contact and apply pressure to the device closest to the pushing element in order

to cause a device to be ejected from the end of the catheter distal to the pushing element at the locus of the conduit.

44. A method as claimed in any of claims 40 to 43, additionally comprising the step of employing a device as claimed in any of claims 12 to 19 to support the catheter within the conduit.

45. A kit comprising at least two of a device as claimed in any of claims 1 to 11, a device as claimed in any of claims 12 to 19, a device as claimed in any of claims 26 to 34, and a device as claimed in any of claims 35 to 39.

46. The use of a device as claimed in any of claims 26 to 34 to dilate the walls of an artery, a vein or a graft.

47. The use of a device as claimed in any of claims 1 to 11 or a device as claimed in any of claims 35 to 39 to retain a graft on the walls of an artery or vein.

# PATENT COOPERATION TREATY

# PCT



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>IT/mh/n8665</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/GB99/02544</b>	International filing date (day/month/year) <b>03/08/1999</b>	Priority date (day/month/year) <b>03/08/1998</b>
International Patent Classification (IPC) or national classification and IPC <b>A61B17/064</b>		
Applicant <b>ANSON MEDICAL LTD. et al.</b>		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 11 sheets, including this cover sheet.  <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of 7 sheets.

3.	This report contains indications relating to the following items: <ul style="list-style-type: none"> <li>I    <input checked="" type="checkbox"/> Basis of the report</li> <li>II   <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV  <input checked="" type="checkbox"/> Lack of unity of invention</li> <li>V    <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI  <input type="checkbox"/> Certain documents cited</li> <li>VII <input checked="" type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>
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Date of submission of the demand  <b>03/03/2000</b>	Date of completion of this report  <b>20.11.2000</b>
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  <b>Kempin, H-F</b>  Telephone No. +49 89 2399 2716  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB99/02544

**I. Basis of the report**

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

**Description, pages:**

1-20 as originally filed

**Claims, No.:**

1-47 with telefax of 30/10/2000

**Drawings, sheets:**

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB99/02544

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 20-25, 35-44, 45(if referring to non-searched claims), 46, 47.

because:

☒ the said international application, or the said claims Nos. 20, 46, 47 relate to the following subject matter which does not require an international preliminary examination (*specify*):  
**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 21-25, 35-44.

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB99/02544

- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-20, 26-34, 45-47.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	12-19
Inventive step (IS)	Yes:	Claims	1-11, 45
	No:	Claims	12-19, 26-34
Industrial applicability (IA)	Yes:	Claims	1-19, 26-34, 45
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**



**Concerning Section I (Basis of report)**

The amendments filed with the fax dated 30.10.2000 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

The features of the characterising portion of **claim 12** were originally disclosed in claim 34, which was **not** dependent on original claim 13, now forming the first part of claim 12 together with features of original claim 16. Therefore, the original claims cannot entirely support the amendment. Furthermore, means for bowing the central section of the support member radially outwards were not originally disclosed in the description or figures either, such means were only disclosed in connection with the dilator (see the description of the function of the pulling wire 119 on pages 17, 18) but not the stabiliser. There is not incitation anywhere that the pulling wire 119 can be used in connection with the supporting/stabilizer device of figure 10. The pusher-wire mentioned at the foot of page 14 in connection with the fixator delivery tube is only used for pushing out the fixator delivery tube.

**Concerning Section III (Non-establishment of opinion ...)**

Claim 46 relates to the use of a device to dilate the walls of an artery. A use claim corresponds to a method claim; see the PCT Preliminary Examination Guidelines CIII-3.1. Claim 46 thus relates to an activity comprising a surgical step, which is dilation of a blood vessel. Accordingly, the claim is directed to subject-matter mentioned in Rule 67.1(iv) PCT. Under the terms of Art.34(4)(a)(i) PCT an International Preliminary Examining Authority is not requested to carry out an examination of such a claim. Claims 20 and 47 relate to the use of a device to support a catheter within a conduit or the use of a device to retain a graft on the walls on an artery or vein, respectively, and thus also implicitly define a surgical activity. Consequently, an examination is not requested as for claims 20 and 46.

**Concerning Section IV (Lack of unity ...)**

1. The International Search Report (ISR) was not established for all claims. Certain

claims were not the object of a search since they relate either to a method for treatment of the human or animal body by surgery, or the required additional search fee was not paid.

2. Only claims in respect of which an ISR was established can be examined. The searched claims comprise 6 independent claims which are claims 1, 12, 20, 26, 46, and 47 (The use claims are considered independent although they refer back to other claims because they refer to claims of a different category). Each independent claim defines an invention since this is the purpose of an independent claim.
3. Under the provisions of Rule 13.1 PCT a group of inventions may be claimed in one application if they are so linked as to form a single general inventive concept. Rule 13.2 of the PCT defines in more detail what is meant with "a single general inventive concept". This concept must find expression in the claims in the same or corresponding special technical features, where the expression "special technical features" means the features which define the inventive contribution that the claimed invention makes over the prior art; see also the PCT Preliminary Examination Guidelines PCT/GL/3 Chapter III-7.1 and 7.2. However, the set of claims forming the basis for examination is objectionable under Rule 13.1-3 PCT since it comprises multiple (groups of) inventions:
  1. Claims 1-11, 45 relate to a staple which is distinguished over the prior art in that it comprises a plurality of first parts.
  2. Claims 12-19 define a catheter support with a locating member and a plurality of support members.
  3. Claims 26-34 are directed to a dilator which differs from the prior art by additionally means to bow the central section of the dilating members radially outwards .

The features of these claims or groups of claims cannot be subsumed under a single general inventive concept since the number of first part on a staple has nothing to do with the design of a catheter support, or means for bowing out the

central section of a dilator.

**Concerning Section V (Reasoned statement ...)**

**First invention as defined in claims 1-11, 45**

1. Reference is made to the following documents:

D1: US-A-5 632 746 (MIDDLEMAN, PYKA ET AL. ) 27 May 1997

D2: US-A-3 527 223 (SHEIN) 8 September 1970

D3: US-A-4 921 484 (HILLSTEAD) 1 May 1990

D4: US-A-4 590 938 (SEGURA ET AL.) 27 May 1986

Document D4 was not cited in the international search report.

- 1.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

A device for retaining tissue on both sides of an incision, comprising a first part for contacting the tissue on one side of the incision and a second part for contacting the tissue on the other side of the incision when the device is pierced through the tissue on both sides of the incision (see reference numeral 8 in figures 2-17A - 17C), the first and second part being connected by a resilient member (see column 25, lines 11, 20 and column 2, lines 51-58), wherein the resilient member biases the first and second part towards each other into a retaining configuration such that in use the tissue parts are retained together between the first and second parts of the device, and wherein the first and second parts are movable into an open configuration in which they are further apart than in the retaining configuration (compare figures 2-12A and 2-12B) to enable the device to be conveyed along an artery (see column 25, lines 15-18). Although it is not expressly mentioned in D1 is that the device can be used for retaining a graft on an artery, it is considered that the known clip is also suitable for retaining graft on an artery so that this feature is implicitly known from D1; see the PCT Preliminary Examination Guidelines CIV-7.6

The device of claim 1 differs from the known device in that it comprises a plurality of first parts. This solves the problem of retaining a graft on an artery in a more secure manner. The distinguishing feature of claim 1 is neither known from, nor rendered obvious by, the available prior art. Although document D2 discloses a wire-like body with sliced ends which can be straightened to align with the body portion (see column 1, line 67 to column 2, line 9), it is considered that D2 discloses a device which is unsuitable for retaining a graft on an artery since it relates to a temporary ear stud of ornamental appearance. D2 would thus not be considered by the skilled person.

Dependent claims 2-11 relate to preferred embodiments of the device of claim 1.

Therefore, claims 1-11 appear to satisfy the requirements of Art.33(2) (novelty), 33(3) (inventive step) and 33(4) (industrial applicability) of the PCT.

- 1.2 Claim 45 relates to a kit comprising at least two of the devices of any of claims 1-11, and thus appears to satisfy the requirements of Art.33(2) (novelty), 33(3) (inventive step) and 33(4) (industrial applicability) of the PCT for the same reasons as these claims.

## **Second invention as defined in claims 12-19**

- 2.1 In the following paragraph the combination of original claims 13 and 16, now claim 12, is discussed; see Basis of Report, point 3.

From document D1 there is known a device for use with a catheter (see figures 5-1, 5-2 and column 46, lines 50-53), the device having a locating member for locating the device with respect to the catheter (see column 46, lines 47-50) and a plurality of support members for supporting the catheter on the inner wall of an artery (see loops 116 and column 47, lines 28-30), wherein each support member and the locating member are connected by a resilient member which biases the support member towards the artery wall (see column 45, lines 9-23).

Although not expressly mentioned in document D1, the device known from figures 5-1 and 5-2 of D1 and described in column 45, line 9 to column 47, line 52 is

suitable to be used as a support for a catheter. In this context it is referred to the access for additional devices mentioned in the paragraph bridging columns 46 and 47. If the loops is extended from the catheter in an artery of suitable dimension they necessarily support the catheter when another instrument is inserted through the additional access provided within the catheter housing. The catheter support functionality is thus implicit from D1.

Therefore, the device of claim 12 does not appear to satisfy the requirement of Art.33(2) PCT (novelty).

- 2.2 Dependent claims 13-19 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:

claim 13, 14: see figure 5-1;

claim 15: see column 47, lines 42-47;

claims 16, 17: see again figure 5-2;

claim 18: see column 47, lines 47-53;

claim 19: see column 45, lines 37-39 and 60-63.

**Third invention as defined in claims 26-34.**

- 3.1 A device having the features of the first part of claim 26 is known from D1 (figures 5-1, 5-2 and column 45, line 9 to column 47, line 53). The particular intended use defined in claim 26 is implicit in the disclosure of D1 since the known retractor is also suitable for dilating an artery.

The device of claim 26 differs from the known device in that it additionally comprises means which can cause the central section of the dilating member to bow radially outwards in order to apply increased outward pressure, as defined in detail in the second part of claim 26.

Thereby, the problem of improving the dilating effect of the known device is solved. However, the distinguishing features have already been employed for the same purpose in a similar device, see document D3, column 4, lines 20-30. It

would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to claim 26. The subject-matter of claim 26 does therefore not involve an inventive step (Article 33(3) PCT).

- 3.2 Dependent claims 27-34 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, the reasons being as follows:

claim 27, 28: see D1, figure 5-1;

claim 29: see D1, column 47, lines 42-47;

claim 30: see again figure 5-2 of D1;

claim 31: see document D4 (cited in D1 in column 44, lines 58, 59), reference numerals 20, 21;

claim 32: see again D3, column 4, lines 20-30

claim 33: see D1 column 47, lines 47-53;

claim 34: see D1 column 45, lines 37-39 and 60-63.

#### **Concerning Section VII (Certain defects ...)**

1. The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
4. The description is not in conformity with the claims as required by Rule 5.1(a)(iii)

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB99/02544

PCT.

## **CLAIMS**

1. A device for retaining a graft on an artery, comprising a first part for contacting the graft and a second part for contacting the artery when the device is pierced radially through the graft and the artery wall, the first and second parts being connected by a resilient member, wherein the resilient member biases the first and second parts towards each other into a retaining configuration such that in use the artery and the graft are retained together between the first and second parts of the device, and wherein the first and second parts are moveable into an open configuration in which they are further apart than in the retaining configuration to enable the device to be conveyed along an artery,  
characterised in that the device comprises a plurality of first parts.
2. A device as claimed in claim 1, wherein in the open configuration the first parts, the resilient member and the second part are disposed substantially on an axis.
3. A device as claimed in claim 1 or 2, wherein in the retaining configuration at least one of the first and second parts forms an arcuate shape.
4. A device as claimed in any preceding claim, wherein at least a portion of at least one of the first and second parts is sharpened to enable said part to pierce a graft and an artery.
5. A device as claimed in claim 4, wherein both the first and the second parts are so sharpened.
6. A device as claimed in any preceding claim, wherein the device is formed from a wire.
7. A device as claimed in any preceding claim, wherein the device is formed from a shape memory alloy.



8. A device as claimed in any preceding claim, wherein the device has a plurality of second parts.
9. A device as claimed in claim 8, wherein the device has equal numbers of first and second parts.
10. A device as claimed in claim 8 or 9, wherein said plurality of parts are integral or welded together.
11. A device as claimed in claim 9, which is formed of a plurality of sets, each set comprising a first part, a resilient member and a second part, wherein the plurality of sets are linked together by a weld, a sheath, a bush, a crimp or by wire.
12. A device for supporting a catheter within an artery or arterial graft, the device having a locating member for locating the device with respect to the catheter and a plurality of support members for supporting the catheter on the inner wall of the artery or graft, wherein each support member and the locating member are connected by a resilient member which biases the support member towards the artery wall,  
characterised in that the device additionally comprises means for reducing the distance between the end of each support member distal to the locating member and the end of said support member proximate the locating member, thereby causing the central section of said support member to bow radially outwards with respect to the locating member.
13. A device as claimed in claim 12, wherein the locating member is adapted to fit axially inside a catheter.
14. A device as claimed in claim 13, wherein the support members and the locating member are moveable into a position in which the support members, the resilient members and the locating member are disposed substantially on an axis, to enable the device to be conveyed along a catheter.

15. A device as claimed in any of claims 12 to 14, wherein each support member is connected to at least one other support member by the end of the support member distal to the locating member.

16. A device as claimed in claim 15, comprising at least one resilient wire disposed in a loop with the ends of the wire being locatable in an end of a catheter, wherein in use the sides of the loop contact the artery or graft to support the catheter within the artery or graft.

17. A device as claimed in any of claims 12 to 16, wherein said plurality of support members are disposed such that in use the device supports the catheter substantially centrally within an artery.

18. A device as claimed in any of claims 12 to 17, wherein each support member has a non-traumatic contact surface for contacting the artery wall.

19. A device as claimed in any of claims 12 to 18 which is formed from a shape memory alloy or a super elastic material.

20. The use of a device as claimed in any of claims 12 to 19 to support a catheter within a conduit.

21. A method for delivering a device as claimed in any of claims 1 to 11 to a locus of a conduit, comprising the steps of moving said first parts and second part of the device into said open configuration, inserting the device into a catheter, positioning an end of the catheter at the locus, and moving the device down the catheter until the device emerges from said end of the catheter at the locus.

22. A method as claimed in claim 21, wherein said end of the catheter is angled radially relative to the axis of the catheter.

23. A method as claimed in claim 21 or 22, additionally comprising the step of housing the catheter within a sheath catheter.

24. A method as claimed in any of claims 21 to 23, comprising the step of inserting a plurality of said devices into the catheter, and inserting a pushing element sufficiently far into the catheter to contact and apply pressure to the device closest to the pushing element in order to cause a device to be ejected from the end of the catheter distal to the pushing element at the locus of the conduit.

25. A method as claimed in any of claims 21 to 24, additionally comprising the step of employing a device as claimed in any of claims 12 to 19 to support the catheter within the conduit.

26. A device for dilating an artery when delivered translumenally to a locus of an artery by means of a catheter, having a locating member for locating the device with respect to the catheter and a plurality of dilating members, each of which is connected to the locating member by a resilient member which biases the dilating member towards and into contact with the inner artery wall, wherein in use the resilient members cause the dilating members to apply outward pressure to the inner artery wall in order to dilate the artery

characterised in that the device additionally comprises means for reducing the distance between the end of each dilating member distal to the locating member and the end of said dilating member proximate the locating member, thereby causing the central section of said dilating member to bow radially outwards with respect to the locating member in order to apply increased outward pressure on the inner wall of the artery when the device is in use.

27. A device as claimed in claim 26, wherein the locating member is adapted to fit axially inside a catheter.

28. A device as claimed in claim 26 or 27, wherein the members and the locating member are moveable into a position in which the locating member, the resilient members and the dilating members are disposed substantially on an axis, to enable the device to be conveyed along a catheter.

29. A device as claimed in any of claims 26 to 28, wherein each dilating member is connected to at least one other dilating member by the end of the dilating member distal to the locating member.

30. A device as claimed in any of claims 26 to 29, comprising at least one resilient wire disposed in a loop with the ends of the wire being locatable in an end of a catheter, wherein in use the sides of the loop contact the inner artery wall and apply outward pressure thereto in order to dilate the artery.

31. A device as claimed in any of claims 26 to 30, wherein said plurality of dilating members are distributed equally radially about the locating member.

32. A device as claimed in any of claims 26 to 31, wherein said means for reducing the distance is an additional connection between the end of each dilating member distal to the locating member and the locating member.

33. A device as claimed in any of claims 26 to 32, wherein each dilating member has a non-traumatic contact surface for contacting the artery wall.

34. A device as claimed in any of claims 26 to 33 which is formed from a shape memory alloy or a super elastic material.

35. A device for retaining a graft on an artery, comprising an elongate member formed of a resilient material which biases said member into a helical configuration, at least one end of the member being sharpened to enable the member to pierce through the graft and the artery

wall, wherein the member is moveable into an open configuration in which it can be conveyed along an artery.

36. A device as claimed in claim 35, wherein in the helical configuration the device has less than 10 turns.

37. A device as claimed in claim 35 or 36, in which the diameter of the helix formed by the member is no less than about seven times the cross-sectional diameter of the member.

38. A device as claimed in any of claims 35 to 37, wherein the member is formed from a shape memory alloy.

39. A device as claimed in any of claims 35 to 38, wherein in said open configuration the device is substantially straight.

40. A method for delivering a device as claimed in any of claims 35 to 39 to a locus of a conduit, comprising the steps of moving said helical member into said open configuration, inserting the device into a catheter, positioning an end of the catheter at the locus, and moving the device down the catheter until the device emerges from said end of the catheter at the locus.

41. A method as claimed in claim 40, wherein said end of the catheter is angled radially relative to the axis of the catheter.

42. A method as claimed in claim 40 or 41, additionally comprising the step of housing the catheter within a sheath catheter.

43. A method as claimed in any of claims 40 to 42, comprising the step of inserting a plurality of said devices into the catheter, and inserting a pushing element sufficiently far into the catheter to contact and apply pressure to the device closest to the pushing element in order

to cause a device to be ejected from the end of the catheter distal to the pushing element at the locus of the conduit.

44. A method as claimed in any of claims 40 to 43, additionally comprising the step of employing a device as claimed in any of claims 12 to 19 to support the catheter within the conduit.

45. A kit comprising at least two of a device as claimed in any of claims 1 to 11, a device as claimed in any of claims 12 to 19, a device as claimed in any of claims 26 to 34, and a device as claimed in any of claims 35 to 39.

46. The use of a device as claimed in any of claims 26 to 34 to dilate the walls of an artery, a vein or a graft.

47. The use of a device as claimed in any of claims 1 to 11 or a device as claimed in any of claims 35 to 39 to retain a graft on the walls of an artery or vein.

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

TOLLETT, I.  
WILLIAMS, POWELL & ASSOCIATES  
4 St.Paul's Churchyard  
LONDON EC4M 8AY  
GRANDE BRETAGNE

## PCT

### NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

Date of mailing  
(day/month/year) 20.11.2000

Applicant's or agent's file reference  
IT/mh/n8665

#### IMPORTANT NOTIFICATION

International application No.  
PCT/GB99/02544

International filing date (day/month/year)  
03/08/1999

Priority date (day/month/year)  
03/08/1998

Applicant  
ANSON MEDICAL LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

 European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Edel, M

Tel. +49 89 2399-2426



## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>IT/N8665</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/GB 99/ 02544</b>	International filing date (day/month/year) <b>03/08/1999</b>	(Earliest) Priority Date (day/month/year) <b>03/08/1998</b>
Applicant <b>ANSON MEDICAL LTD. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.

3



None of the figures.



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB 99/02544

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-27, 43-47  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:  
1-22, 28-37, 48-50
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-12,48,50

Staple

2. Claims: 13-22

Catheter support

3. Claims: 28-37,49

Dilator

4. Claims: 38-42,50

Spiral fixing

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/02544

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/064 A61B17/22 A61F2/06 A61M29/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 527 223 A (SHEN) 8 September 1970 (1970-09-08) figures 1,3,5 ---	1-3,6-12
X	US 5 632 746 A (PYKA) 27 May 1997 (1997-05-27) figures 212,321 ---	1-4,6
A	---	17,21, 31,37
X	US 3 716 058 A (TANNER) 13 February 1973 (1973-02-13) column 2, paragraph 3; figure 4 ---	1,4,5
A	FR 2 746 292 A (PEROUSE) 26 September 1997 (1997-09-26) figures 2,7,8,18 ---	1,4
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## ° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

13 March 2000

Date of mailing of the international search report

28.03.2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Barton, S

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/02544

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 618 311 A (GRYSKIEWICZ) 8 April 1997 (1997-04-08) figure 1	5
A	FR 2 725 126 A (MAI) ✓ 5 April 1996 (1996-04-05) figure 9C	8-11
A	US 5 531 760 A (ALWAFIAE) 2 July 1996 (1996-07-02)	
X	US 4 921 484 A (HILLSTEAD) 1 May 1990 (1990-05-01)  column 1, paragraph 1 column 5, line 18 column 5, line 53 - line 58	13-16, 19-22, 28-30, 33-37
A	US 5 330 490 A (WILK) 19 July 1994 (1994-07-19) column 9, paragraph 2; figures 9-12	31
X	US 5 222 971 A (WILLARD) 29 June 1993 (1993-06-29) column 4, line 39 - line 43 column 11, line 59 - line 66 column 13, line 35 - line 39	13,22
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## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 99/02544

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